IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAMLAB, L.L.C., METABOLITE LABORATORIES, INC., and BRECKENRIDGE PHARMACEUTICAL, INC.,	)	
Plaintiffs,	)	C.A. No.
v.	)	JURY TRIAL DEMANDED
ACELLA PHARMACEUTICALS, LLC,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Pamlab, L.L.C., Metabolite Laboratories, Inc., and Breckenridge Pharmaceutical, Inc., by and through their attorneys, state as follows for their Complaint against Defendant Acella Pharmaceuticals, LLC:

THE PARTIES

1. Plaintiff Pamlab, L.L.C. ("Pamlab") is a limited liability company organized and existing under the laws of the State of Louisiana, with its principal place of business at 4099 Highway 190, Covington, Louisiana, 70433.

2. Plaintiff Metabolite Laboratories, Inc. ("Metabolite") is a corporation organized and existing under the laws of the State of Colorado, with its principal place of business at 1133 14th Street, Unit 3600, Denver, Colorado 80202.

3. Plaintiff Breckenridge Pharmaceutical, Inc. ("Breckenridge") is a corporation organized and existing under the laws of the State of Florida, with its principal place of business at 1141 South Rogers Circle, Suite 3, Boca Raton, Florida 33487.

4. Defendant Acella Pharmaceuticals, LLC ("Acella") is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at 9005 Westside Parkway, Alpharetta, Georgia 30004.

JURISDICTION AND VENUE

5. This Court has original jurisdiction over the subject matter of this lawsuit under 28 U.S.C. §§ 1331 and 1338(a), because it arises under the patent laws of the United States, as well as under 28 U.S.C. § 1331 and 15 U.S.C. § 1221(a), because it concerns violations of section 43 of the Lanham Act, 15 U.S.C. § 1125; this Court has supplemental jurisdiction over the state law claims herein pursuant to 28 U.S.C. § 1367, because the subject matter is so related to the claims asserted under federal law as to form part of the same case or controversy.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1400 and 1391, because Acella is a Delaware entity. Acella is also subject to personal jurisdiction in this district because it markets and sells products to nationwide retail drug store chains, including those with locations within this judicial district, as well as through nationwide distributors and databases that target this judicial district.

STATEMENT OF FACTS

The Research Leading to the Patent in Suit and Pamlab's Patent License

7. Homocysteine is an amino acid and a natural byproduct of the human body's conversion of methionine into cysteine. If a body lacks the enzyme necessary to complete that conversion, or if the body lacks vitamins such as folic acid, B_6 and B_{12}, the concentration of homocysteine in the blood and urine increases.

8. In recent years, researchers have identified an increased homocysteine level in the blood (hyperhomocysteinemia) as an additional and independent risk factor for arteriosclerosis

and coronary heart diseases. Similarly, hyperhomocysteinemia is linked with repeatedly occurring venous thromboses and apoplexy strokes.

9. Studies have shown that a combination of vitamins B_6, B_{12}, and folic acid can lower homocysteine levels in most patients. Thus, doctors increasingly recommend that their patients with elevated homocysteine levels take supplements of vitamin B_6, vitamin B_{12}, and especially folic acid.

10. Some years ago, Plaintiff Pamlab noted the medical interest in treating elevated homocysteine levels with vitamin $B_{12,}$ vitamin B_6, and folic acid (also known as folate), and decided to formulate a product having these vitamins in suitable quantities. During the development of this product, Pamlab discovered the groundbreaking work of two hematology professors at the University of Colorado School of Medicine, Dr. Robert H. Allen and Dr. Sally P. Stabler.

11. Drs. Allen and Stabler have devoted their careers to studying vitamin $B_{12,}$ vitamin B_6, and folate. Their clinical work has been at the forefront of the research examining the relationship between those vitamins and homocysteine. Their studies have been widely cited and published in prestigious scientific journals such as the New England Journal of Medicine, and they have also been awarded a number of United States patents.

12. Among these is United States Patent No. 6,528,496, entitled "Compositions treating, preventing, or reducing elevated metabolic levels" ("the '496 Patent"), which was duly and legally issued to Drs. Allen and Stabler on March 4, 2003. The '496 Patent is attached as Exhibit A.

13. Dr. Allen formed Plaintiff Metabolite under the University of Colorado's guidelines. The patents and applications leading to the '496 Patent, and later the '496 Patent

itself, were assigned to Metabolite, so that Metabolite is the owner of all right, title, and interest in the '496 Patent, as well as the related patents.

14. Accordingly, Pamlab approached Metabolite in 1999 and began discussions concerning a patent license for certain products. Pamlab first launched the product at issue (as discussed hereinafter) in the fall of 1999, while these discussions were in progress. Then on January 11, 2000, Pamlab entered into a license agreement with Metabolite (the "Patent License"), under which Metabolite granted Pamlab an exclusive license to certain formulations under several related patents and applications (one of which, through a subsequent continuation application, issued as the '496 Patent). Moreover, under the Patent License (as amended), Pamlab has the right to enforce the '496 Patent.

Pamlab's Licensed Product Foltx®

15. Pursuant to the Patent License, Pamlab manufactures and sells a product with the trademarked name of "Foltx®." Pamlab pays Metabolite a royalty based on the value of the sales of Foltx®.

16. Foltx® is marketed to licensed physicians and other healthcare professionals.

17. Foltx® contains three active ingredients, namely vitamin B_{12}, vitamin B_6, and folic acid. When Foltx® was first marketed by Pamlab in October, 1999, it contained 1 mg. of vitamin B_{12}, 25 mg. of vitamin B_6, and 2.5 mg. of folic acid. Beginning in June, 2004, Pamlab introduced Foltx® containing 2 mg. of vitamin B_{12} instead of 1 mg., and discontinued sales of the 1 mg. Foltx®.

18. After Pamlab launched Foltx® in October, 1999, the market for this product grew steadily as physicians increasingly recognized the relationship between elevated homocysteine and vitamin B_{12}, vitamin B_6, and folate.

19. Much of this recognition is attributable to the huge investment in education that Pamlab has undertaken. Pamlab has spent millions of dollars calling on tens of thousands of physicians through Pamlab's sales force, providing millions of product samples, publishing articles and advertisements in medical journals, and funding additional clinical studies.

20. Pamlab markets Foltx® to physicians as a medical food product intended for the specific dietary management of individuals under a physician's treatment for hyperhomocysteinemia, with particular emphasis on individuals with or at risk for atherosclerotic vascular disease in the coronary, peripheral, or cerebral vessels, or individuals with vitamin B_{12} deficiency.

Breckenridge's Patent Sublicense and Its Licensed Folic Acid Product

21. In 2007, Breckenridge entered into a patent sublicense with Pamlab under a number of the Metabolite patents, with the express consent of Metabolite, including but not limited to the '496 Patent, and including the right to enforce the '496 Patent. This agreement also provides Breckenridge with additional rights to be the exclusive marketer of generic versions of the Pamlab products identified therein.

22. Under this agreement, Breckenridge now markets the only licensed generic version of Foltx®. Breckenridge markets a product containing 2 mg. of vitamin B_{12}, 25 mg. of vitamin B_6, and 2.5 mg. of folic acid as "Folbic®".

23. Breckenridge pays a royalty to Pamlab pursuant to the sublicense, which in turn pays a royalty to Metabolite.

Acella's Folic Acid Product, "Folastin"

24. Acella has manufactured or had manufactured, for sale in the United States, a product which it represents to contain 2 mg. of vitamin B_{12}, 25 mg. of vitamin B_6, and 2.5 mg. of

folic acid, the same active ingredients in the same amounts as Foltx® and Folbic®, and which Acella markets under the name of "Folastin."

25. Upon information and belief, Acella either directly represents that its Folastin contains these amounts of these active ingredients, or made such representations as were necessary to cause one or more industry databases to represent to the industry that its Folastin contains 2 mg. of vitamin B_{12}, 25 mg. of vitamin B_6, and 2.5 mg. of folic acid.

26. Acella has offered its Folastin for sale in commerce in the United States.

27. Upon information and belief, in offering its Folastin for sale, Acella has represented, explicitly or implicitly, that its Folastin is substitutable for Foltx® and/or Folbic®.

28. Upon information and belief, Acella has not scientifically determined whether its Folastin is substitutable for Foltx® and/or Folbic®.

29. Upon information and belief, Acella did not perform the industry-standard testing necessary to support the claims and representations contained in Folastin's labeling.

COUNT I
Patent Infringement

30. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

31. By manufacturing, offering to sell, and (if successful) by selling its Folastin, Acella has infringed and is infringing the '496 Patent under 35 U.S.C. section 271(a), literally and/or under the doctrine of equivalents, and/or by having its Folastin manufactured to contain the active ingredients in the amounts specified above, with knowledge that its Folastin would infringe the '496 Patent, Acella has induced infringement of and/or contributed to the infringement of the '496 Patent under 35 U.S.C. section 271 (b) and/or (c).

32. Plaintiffs have been injured thereby, in an amount to be determined at trial.

33. Upon information and belief, the infringement of the '496 Patent by Acella has been and is willful.

34. Upon information and belief, Acella will continue its infringement of the '496 Patent unless its acts of infringement are restrained and enjoined by this Court. Should Acella be permitted to continue its acts of infringement of the '496 Patent, Plaintiffs will suffer irreparable injury for which they have no adequate remedy at law.

COUNT II
Violation Of The Lanham Act

35. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

36. In the alternative, and/or in addition, Acella has misrepresented the active ingredients and/or the amounts thereof contained in its Folastin, which constitutes false and/or misleading descriptions and representations of fact that misrepresent the nature, characteristics, and/or qualities of Acella's Folastin, and otherwise constitutes false advertising under section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

37. Upon information and belief, Acella did not perform the industry-standard testing necessary to support the claims and representations contained in Folastin's labeling. In addition, upon information and belief, because Acella has not scientifically determined whether its Folastin is pharmaceutically equivalent to Foltx® and/or Folbic®, the explicit or implied representations by Acella, in commerce, that its Folastin is substitutable for Foltx® and/or Folbic® are also false and/or misleading. The foregoing are descriptions and representations of fact that misrepresent the nature, characteristics, and/or qualities of Acella's Folastin, and otherwise constitute false advertising in violation of section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

38. Acella's false and misleading explicit and/or implicit representations go to an inherent quality or characteristic of Folastin.

39. Upon information and belief, Acella's false and misleading explicit and/or implicit representations have been made in interstate commerce, are material, have influenced purchasing decisions in this District and elsewhere, and will continue to do so unless enjoined.

40. Plaintiffs have been and/or will be injured thereby, in an amount to be determined at trial.

41. Upon information and belief, Acella will continue its violations of the Lanham Act unless such acts are restrained and enjoined by this Court. Should Acella be permitted to continue its false and/or misleading descriptions and representations of fact and false advertising, Plaintiffs will suffer irreparable injury for which they have no adequate remedy at law.

COUNT III
Common Law Unfair Competition

42. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

43. Plaintiffs, based on their years of marketing efforts and their established sales of Foltx® and Folbic®, had a reasonable and legitimate business expectancy of continuing such sales.

44. The acts of Acella alleged above, including its various false and/or misleading representations of fact concerning the characteristics, ingredients, and qualities of its Folastin, have wrongfully interfered with this expectancy, and thus constitute unfair competition.

45. Plaintiffs have been and/or will be injured thereby, in an amount to be determined at trial.

46. Upon information and belief, Acella will continue its acts of unfair competition unless such acts are restrained and enjoined by this Court. Should Acella be permitted to continue its unfair competition, Plaintiffs will suffer irreparable injury for which they have no adequate remedy at law.

COUNT IV
Violation Of The Delaware Uniform Deceptive Trade Practices Act

47. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

48. The acts of Acella alleged above, including its false and/or misleading representations of fact concerning the characteristics, ingredients, and qualities of Acella's Folastin, constitute deceptive trade practices in violation of the Delaware Uniform Deceptive Trade Practices Act, Del. C. § 2531 *et seq.*

49. Upon information and belief, Acella's false and misleading explicit and/or implicit representations are material and have influenced purchasing decisions in this District, and elsewhere, and will continue to do so unless enjoined.

50. By reason of Acella's unlawful actions, Plaintiffs will suffer irreparable harm for which there is no adequate remedy at law. Accordingly, Plaintiffs are entitled to an injunction against Acella, pursuant to Del. C. § 2533(a).

51. Plaintiffs have suffered and continue to suffer losses from the unlawful actions of Acella, and are entitled to recover treble such damages sustained as a result of these actions and awarded to them for Count III, *supra*, pursuant to Del. C. § 2533(c).

52. Acella's violations of the Delaware Uniform Deceptive Trade Practices Act were willful, such that Plaintiffs are entitled to recover attorneys fees and court costs, pursuant to Del. C. § 2533(b).

WHEREFORE, Plaintiffs request that the Court:

(a) Preliminarily and permanently enjoin Acella, its officers, directors, employees, partners, agents, licensees, servants, successors and assigns, and any and all persons acting in privity or concert with them, from making, having made, using, offering to sell, or selling Acella's Folastin;

(b) Enter judgment against Acella for compensatory damages by reason of its infringement of the '496 Patent, as determined at trial, but not less than a reasonable royalty, in an amount to be determined at trial;

(c) Determine that such infringement was willful, and award treble damages to Plaintiffs by reason thereof;

(d) Declare this case to be "exceptional" within the meaning of 35 U.S.C. § 285, entitling Plaintiffs to an award of their reasonable attorneys fees, expenses and costs of this action;

(e) Preliminarily and permanently enjoin Acella, its officers, directors, employees, partners, agents, licensees, servants, successors and assigns, and any and all persons acting in privity or concert with them, from representing, explicitly or implicitly, that Acella's Folastin is substitutable for Foltx® and/or Folbic®, and from making any other false and misleading statements and representations concerning Folastin, as determined at trial;

(f) Enter judgment against Acella for compensatory damages by reason of its violation of the Lanham Act, in an amount to be determined at trial;

(g) Enter judgment against Acella for compensatory damages by reason of its unfair competition, in an amount to be determined at trial, and for treble such damages pursuant to Del. C. § 2533(c);

(h) Determine that Acella's violation of the Delaware Uniform Deceptive Trade Practices Act was willful, and enter judgment against Acella for Plaintiffs' costs and attorneys' fees pursuant to Del. C. § 2533(b); and

(i) Enter an Order granting Plaintiffs such other and additional relief against Acella as may be just and proper in the circumstances.

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs demand a trial by jury of all issues properly triable to a jury in this case.

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